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4164-01-P
DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Parts 314 and 320
[Docket No. FDA-2011-N-0830]
RIN 0910-AF97
Abbreviated New Drug Applications and 505(b)(2) Applications

Correction

In Proposed Rule Document 2015-01666, pages 6801-6896, publishing in the Issue of Friday, February 6, 2015, make the following corrections:

1. On page 6807, in the second column in Table 1, the heading should read:

<p style="text-align: center;">Proposed Changes See section of this document (identified in parentheses) for more detailed information regarding the proposed change.</p>
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2. On page 6808, in Table 1, the second column should read:

314.95(e)	<p>Documentation of Timely Sending and Receipt of Notice of Paragraph IV Certification, including:</p> <p>a. Acceptable methods of sending notice of paragraph IV certification; and</p> <p>b. Amendment documenting timely sending and confirmation of receipt of notice of paragraph IV certification</p> <p>(II.D.4)</p>
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3. On pages 6818-6819, in Table 2, the second row should read:

Current Regulations	Proposed Revisions to Regulations
<p><u>General Requirements (§ 314.53(c)(1))</u></p> <p>Patent information will not be accepted unless it is complete and submitted on the appropriate forms (Form FDA 3542a or 3542).</p>	<p><u>General Requirements (§ 314.53(c)(1))</u></p> <ul style="list-style-type: none"> • Patent information will not be accepted unless it is submitted on the appropriate forms (Form FDA 3542a or 3542) and contains the information required in § 314.53(c)(2).
<p><u>Reporting Requirements (§ 314.53(c)(2))</u></p> <p>The required information and verification in § 314.53(c)(2)(i) and (c)(2)(ii) includes:</p> <ul style="list-style-type: none"> • Information on whether the patent has been submitted previously for the NDA. • Information on whether the drug substance patent claims a polymorph that is the same active ingredient that is described in the pending NDA or supplement, and, if so, has test data described in § 314.53(b)(2). 	<p><u>Reporting Requirements (§ 314.53(c)(2))</u></p> <p>The required information and verification in § 314.53(c)(2)(i) and (c)(2)(ii) includes:</p> <ul style="list-style-type: none"> • Information on whether the patent is a re-issued patent of a patent submitted previously for listing for the NDA or supplement. • Information on whether the drug substance patent claims <u>only</u> a polymorph that is the same active ingredient that is described in the pending NDA or supplement, and, if so, has test data described in § 314.53(b)(2).

4. On pages 6838-6839, in Table 8, the second row should read:

Current Regulations	Proposed Revisions to Regulations
<p><u>Documentation of receipt of notice (§§ 314.52(e) and 314.95(e))</u></p> <ul style="list-style-type: none"> • Applicant must amend its 505(b)(2) application or ANDA to document the date of receipt of the notice of paragraph IV certification by each patent owner and NDA holder provided the notice. • Applicant must include a copy of the return receipt or other similar evidence of the date the notification was received. -- FDA will accept as adequate documentation of the date of receipt a return receipt or a letter acknowledging receipt by the person provided the notice. • An applicant may rely on another form of documentation only if FDA has agreed to such documentation in advance. 	<p><u>Documentation of timely sending and receipt of notice (§§ 314.52(e) and 314.95(e))</u></p> <ul style="list-style-type: none"> • Applicant must amend its 505(b)(2) application or ANDA to provide documentation of the date of receipt of the notice of paragraph IV certification by each patent owner and NDA holder provided the notice. --FDA will accept as adequate documentation of the date of receipt a return receipt, signature proof of delivery by a designated delivery service, or a letter acknowledging receipt by the person provided notice. -- Amendment must be submitted to FDA within 30 days after the last date on which notice was received by a patent owner or NDA holder. • Amendment also must include adequate documentation that notice was sent on a date that complies with the timeframe required by § 314.52(b) or (d) or § 314.95(b) or (d), as applicable. --FDA will accept a copy of the registered mail receipt, certified mail receipt, or receipt from a designated delivery service, as adequate documentation of the date of delivery. • An ANDA applicant's amendment must include a dated printout of the Orange Book entry for the RLD that includes the patent that is the subject of the paragraph IV certification. • An applicant may rely on another form of documentation only if FDA has agreed in advance.

5. On pages 6842-6843, in Table 9, the third row should read:

Current Regulations	Proposed Revisions to Regulations
<u>After a Finding of Infringement</u> <u>(§§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A))</u> <ul style="list-style-type: none">• Change from paragraph IV certification to paragraph III certification required after a final judgment is entered finding the patent to be infringed.• Provision applies if patent infringement action initiated within 45 days of receipt of notice of paragraph IV certification.	<u>After a Finding of Infringement</u> <u>(§§ 314.50(i)(6)(i) and 314.94(a)(12)(viii)(A))</u> <ul style="list-style-type: none">• Change from paragraph IV certification to paragraph III certification required after court enters final decision from which no appeal has been or can be taken, or signs settlement order or consent decree with a finding of infringement (unless the patent also is found invalid). An applicant may instead provide a statement under § 314.50(i)(1)(iii) or § 314.94(a)(12)(iii) with respect to a method-of-use patent if the 505(b)(2) application or ANDA is amended such that the applicant is no longer seeking approval for a method of use claimed by the patent.• Provision applies if patent infringement action initiated after receipt of notice of paragraph IV certification, irrespective of whether the action is brought within the 45-day period.

6. On pages 6859-6861, in Table 12, the third, sixth, and seventh rows should read:

Current Regulations	Proposed Revisions to Regulations
<p><u>Date of approval letter (§ 314.107(b)(1))</u></p> <ul style="list-style-type: none"> Except as provided in § 314.107(b)(3), (b)(4), and (c), approval will become effective on the date FDA issues an approval letter if the applicant certifies that: <ul style="list-style-type: none"> (i) there are no relevant patents; or (ii) the patent information has not been submitted to FDA; or (iii) the relevant patent has expired; or (iv) the relevant patent is invalid, unenforceable, or will not be infringed. 	<p><u>Timing of approval based on patent certification or statement (§ 314.107(b)(1))</u></p> <ul style="list-style-type: none"> If none of the reasons in § 314.125 or § 314.127 for refusing to approve the application apply, and none of the reasons in § 314.107(d) for delaying approval apply, the 505(b)(2) application or ANDA may be approved-- <ul style="list-style-type: none"> (i) <u>Immediately</u>, if the applicant certifies that: <ul style="list-style-type: none"> (A) the patent information has not been submitted to FDA; or (B) the relevant patent has expired; or (C) the relevant patent is invalid, unenforceable, or will not be infringed, except as provided in § 314.107(b)(3) and (c), and the 45-day period provided for in section 505(c)(3)(C) and 505(j)(5)(B)(iii) of the FD&C Act has expired; or (D) there are no relevant patents. (ii) <u>Immediately</u>, if the applicant submits an appropriate statement explaining that a method-of-use patent does not claim an indication or other condition of use for which it is seeking approval.

Disposition of patent litigation
(§ 314.107(b)(3)(i))

- (A) Except as provided in § 314.107(b)(3)(ii) through (b)(3)(iv), if
-- applicant submits a paragraph IV certification; and
-- patent owner or its representative or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt by the patent owner of the notice of paragraph IV certification,

Approval may be made effective 30 months after the date of the receipt of the notice of paragraph IV certification by the patent owner or by the exclusive licensee (or their representatives) unless the court has extended or reduced the period; or

- (B) If the patented drug product qualifies for 5-year exclusivity, and
-- patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved and within 45 days of receipt by the patent owner of the notice of paragraph IV certification,

Approval may be made effective at the expiration of 7½ years from the date of NDA approval for the patented drug product.

Disposition of patent litigation (§ 314.107(b)(3)(i))

- (A) Except as provided in § 314.107(b)(3)(ii) through (b)(3)(viii), if, with respect to patents for which required information was submitted before the date on which the 505(b)(2) application or ANDA was submitted to FDA (excluding an amendment or supplement),
--applicant submits a paragraph IV certification; and
--patent owner or the exclusive patent licensee brings suit for patent infringement within 45 days of receipt of the notice of paragraph IV certification, 505(b)(2) application, or ANDA may be approved 30 months after the later of the date of the receipt of the notice of certification by any owner of the listed patent or by the NDA holder who is an exclusive patent licensee (or their representatives) unless the court has extended or reduced the period; or

- (B) If the patented drug product qualifies for 5-year exclusivity, and
--patent owner or its representative or the exclusive patent licensee brings suit for patent infringement during the 1-year period beginning 4 years after the date the patented drug was approved and within 45 days of receipt of the notice of paragraph IV certification,

the 505(b)(2) application or ANDA may be approved at the expiration of 7½ years from the date of NDA approval for the patented drug product.

Disposition of patent litigation
(§ 314.107(b)(3)(ii)-(b)(3)(iv))

If before the expiration of the 30-month period, or 7½ years where applicable:

- (ii) the court issues a final order that the patent is invalid, unenforceable, or not infringed, approval may be made effective on:
-- the date the court enters judgment;
- (iii) the court issues a final order or judgment that the patent has been infringed, approval may be made effective on:
-- the date the court determines that the patent will expire or otherwise orders
- (iv) the court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement, and if the court later decides that the patent is invalid, unenforceable, or not infringed, approval may be made effective on:
-- the date the court enters a final order or judgment that the patent is invalid, unenforceable, or not infringed.

Disposition of patent litigation (§ 314.107(b)(3)(ii)-(b)(3)(viii))

If before the expiration of the 30-month period, or 7½ years where applicable:

- (ii) the district court decides that the patent is invalid, unenforceable, or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the 505(b)(2) application or ANDA may be approved on:
--(A) the date on which the court enters judgment reflecting the decision; or
--(B) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed.
- (iii) the district court decides that the patent has been infringed and the judgment is appealed, the 505(b)(2) application or ANDA may be approved on:
--(A) the date on which the mandate is issued by the court of appeals entering judgment that the patent is invalid or not infringed; or
--(B) the date of a settlement order or consent decree signed and entered by the court of appeals stating that the patent is invalid or not infringed.
- (iv) the district court decides that the patent has been infringed and the judgment is not appealed or is affirmed, the 505(b)(2) application or ANDA may be approved no earlier than the date specified by the district court in an order under 35 U.S.C. 271(e)(4)(A).
- (v) the district court grants a preliminary injunction prohibiting the applicant from engaging in the commercial manufacture or sale of the drug product until the court decides the issues of patent validity and infringement:
-- if the court later decides the patent is invalid, unenforceable, or not infringed, the 505(b)(2) application or ANDA may be approved per § 314.107(b)(3)(ii).
--if the court decides that the patent has been infringed, the 505(b)(2) application or ANDA may be approved per § 314.107(b)(3)(iii) or (b)(3)(iv), as applicable.
- (vi) the patent owner or the exclusive patent licensee (or their representatives) agrees in

	<p>writing that the 505(b)(2) application or ANDA may be approved any time on or after the date of the consent, approval may be granted on or after that date.</p> <ul style="list-style-type: none">• (vii) the court enters an order requiring the 30-month or 7½-year period to be terminated, the 505(b)(2) application or ANDA may be approved in accordance with the court's order.• (viii) the court enters an order of dismissal, with or without prejudice, without a finding of infringement, the 505(b)(2) application or ANDA may be approved on or after the date of the order.
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